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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,629	05/14/2001	Morten Jorsboe	9192.15USWO	6531
23552	7590	12/22/2003	EXAMINER	
MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903			KALLIS, RUSSELL	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 12/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

S.M.

Office Action Summary**Application No.**

09/762,629

Applicant(s)

JORSBOE ET AL.

Examiner

Russell Kallis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 74-90 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 74-90 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 May 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

DETAILED ACTION

Applicant's renumbering of the second claim 75 and original Claims 76-89 as Claims 76 and 77-90, respectively, is acknowledged.

The rejection of Claims 74-75, 78-85 and 87-88 (as originally numbered) under 35 U.S.C. 102(b) is withdrawn in view of Applicant's arguments.

The rejection of Claims 74-75, 78-89 (as originally numbered) under 35 U.S.C. 103(a) is withdrawn in view of Applicant's arguments.

The rejection of Claims 80-85 (as originally numbered) under 35 U.S.C. 112, second paragraph is withdrawn in view of Applicant's amendments and arguments.

Claim Rejections - 35 USC § 112

Claims 74-90 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 2/12/2003. Applicant's arguments filed 10/07/2003 have been considered but are not deemed persuasive.

Applicant asserts that the polynucleotides encoding enzymes that convert galactose to UDP-glucose are well known in the art and available via public databases and that the disclosure provides adequate written description for the invention as claimed (response page 6). Applicant further asserts that the enzyme classification numbers will allow one of ordinary skill in the art to ascertain the identity of these polynucleotides encoding the said enzymes (response page 6).

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The specification does not disclose the sequence identity of a representative number of sequences for the broad category of polynucleotides encoding any enzyme "useful to convert galactose to UDP-glucose" (as broadly claimed in Claims 74 and 81-90), including an UTP-dependent pyrophosphorylase, an UDP-glucose-dependent uridyl transferase, a galactokinase, or an UDP-glucose epimerase or set forth regions of the polynucleotides that would allow for one of skill in the art to correlate structure with function so as to discern those sequence of the invention (see MPEP 2163). Further, the public databases that Applicant claims as support for a written description of the above categories of polynucleotides encoding the enzymes that convert galactose to UDP-glucose are often updated or indicate a putative function and the information is either incorrect or subject to change. Furthermore, it is not clear from Applicant's disclosure that those public sequences were made available to the public at the effective filing date.

Applicant has asserted that the Examiner has failed to rebut the disclosure as providing adequate written description (response page 7).

The Examiner reiterates the previous rejection of 2/12/2003; Applicant has not provided that which is necessary to practice the invention, namely the sequence identity of a representative number of sequences of each the broadly claimed genera of polynucleotides that convert galactose to UDP-glucose. Furthermore, the mere disclosure of an amino acid sequence does not adequately describe a nucleic acid sequence, as taught by Lilly cited previously. The sequence listing does not provide for any amino acid sequence from the broadly claimed genera other than the *E. coli galT* sequence of SEQ ID NO: 2. Moreover, Claims 74 and dependent Claims 81-90 are not limited to any discrete amino acid or polynucleotide sequences whatsoever.

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Claims 74-90 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for transformation of potato and seed rape cells and tissue using the *E. coli galT* gene and selection for transformed plant material, does not reasonably provide enablement for transformation of all types of cells and tissues either from plants, animals or bacteria using the *E. coli galT* gene or transformation using any other polynucleotide encoding an enzyme that enhances conversion of galactose to UDP-glucose. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. This rejection is maintained for the reasons of record set forth in the Official action mailed 2/12/2003.

Applicant's arguments filed 10/07/2003 have been considered but are not deemed persuasive.

Applicant asserts that the Examples that teach potato and oil seed rape transformation using the *GalT* gene from *E. coli* and selection using galactose taught in the specification enables the full scope of all plants and all polynucleotides from any one of the claimed four enzyme genera (response page 8) because it is well known that galactose is toxic to plants and the polynucleotide encoding the enzymes are well known.

The Examiner maintains that there is inadequate guidance in the specification for the identification or isolation of a multitude of non-exemplified polynucleotides encoding a multitude of non-exemplified enzymes, as discussed previously. Thus, undue experimentation would have been required by one of skill in the art to isolate these polynucleotides and incorporate them into the claimed method of using said polynucleotides, particularly in view of the claim breadth and unpredictability as set forth previously.

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Applicant asserts that the rate limiting effect of endogenous plant UDP-galactose epimerase was overcome, or shown to be non-limiting, in their transformation experiments by the successful selection of cells transformed with UDP-glucose dependent uridyl transferase an enzyme upstream to UDP-glucose epimerase (response pages 9-10).

The rate limitation of endogenous plant UDP-galactose epimerase was overcome using the *E. coli galT* gene. However, that was not demonstrated with any of the other broadly claimed enzymes that have different mechanisms for being "useful to convert galactose to UDP-glucose", and different levels of activity. It would require undue trial and error experimentation to test non-exemplified genes in a multitude of non-exemplified plant species for usefulness to convert galactose to UDP-glucose".

Applicant asserts that the claims would exclude from their scope any transformed cells with rate limiting steps that would negate the selective advantage of the transgene and that it would not be an undue burden to adapt the invention using the enzymes useful in the conversion of galactose to UDP-glucose (response page 11).

See *In re Fisher*, 166 USPQ 18, 24(CCPA 1970) which teaches "That paragraph (35 USC 112, first) requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art. In cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. In cases involving unpredictable factors, such as most chemical reactions and physiological

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activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved."

In addition, Applicant has not responded to the enablement rejection with respect to Pasco-Gaunt S. *et al.* that the screening for plants that escape the selection process is unpredictable and requires further experimentation to determine the best conditions of selection for each and every variety or species claimed and when the optimal time for selection should occur in order to recover transformed material. (Pasco-Gaunt S. *et al.* Journal of Experimental Botany; Vol. 52, No. 357; pp. 865-874 on page 873 column 1, 2nd full paragraph, the entire paragraph). Also, See *in re Fisher supra*.

Given the lack of guidance for selecting cells or plants transformed with polynucleotides encoding enzymes that enhance the conversion of galactose to UDP-glucose other than transformation of potato and seed rape cells and tissue using the *E. coli galT* gene, and given the breadth of the claims and the unpredictability in the art, undue trial and error experimentation would be needed by one skilled in the art to evaluate the efficiency of selection in a multitude of non-exemplified cell or plant species transformed with any number of non-exemplified polynucleotides encoding enzymes that convert galactose to UDP-glucose. Therefore, the invention is not enabled for the scope set forth in the claims.

All claims are rejected.

Claims 74-90 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest a method of selecting for transformed plant cells resistant to galactose transformed with polynucleotides encoding enzymes that convert galactose to UDP-glucose.

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Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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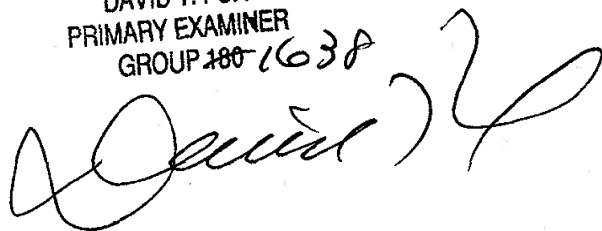
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (703) 305-5417. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0198.

Russell Kallis Ph.D.
December 12, 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180-1638

A large, stylized handwritten signature in black ink, appearing to read 'David T. Fox', is written over the printed name and group number.